Application granted. A conference has been scheduled for August 28, 2025 at 3:30 p.m. to be held in Courtroom 620 of the White Plains courthouse.

SO ORDERED.

Philip M. Halpern
United States District Judge

Dated: White Plains, New York
August 20, 2025

August 18, 2025

VIA ECF
Hon. Philip M. Halpern
Southern District of New York
300 Quarropas St. Courtroom 520
White Plains, NY 10601

Re: *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.*, No. 7:20-cv-05502 (PMH) (S.D.N.Y.) – Joint Letter Regarding Deposition Dispute

Dear Judge Halpern:

Pursuant to L.R. § 37.2 and Rules 2(C) and 4(D) of Your Honor's Individual Practices, Plaintiff Regeneron submits this letter jointly with the Novartis Defendants to respectfully request a conference to resolve a dispute concerning Novartis' 30(b)(6) Topic No. 36 to Regeneron. The parties are at an impasse, and their respective positions are below. To the extent these issues remain unresolved, Regeneron seeks authorization to file a motion for a protective order against Novartis' 30(b)(6) Topic No. 36.

Regeneron's Position: Novartis' 30(b)(6) Topic No. 36 to Regeneron requests testimony concerning the "prosecution of U.S. Patent Application No. 17/930,373" (the "'373 Application"), which is a patent application that Regeneron filed in 2022. Ex. 1 at 15. During the parties' meet and confer, Novartis asserted that this topic is directed to Regeneron's purported disclosure or non-disclosure of a prior art reference ("Sigg Application") during the prosecution of the '373 Application. Ex. 2 at 2. Novartis has also asserted that it intends to elicit testimony via Topic No. 36 concerning Regeneron's general practices of disclosing prior art references during prosecution, which is clearly not within the scope of Topic No. 36 as written. *Id.* at 3.

The Court should grant Regeneron's motion for a protective order against Topic No. 36. First, the information sought by this topic is irrelevant to any issues in this case. *In re Life Litigation*, 2023 WL 3244517 at *2 (S.D.N.Y. May 4, 2023) ("All 30(b)(6) deposition

topics…must seek information relevant to the claims and defenses."). One of Regeneron's claims in this case is based on Novartis' fraudulent withholding of material prior art references during prosecution of Novartis's '352 Application, including the Sigg Application. Dkt. 88 ¶¶ 218-232. Regeneron's purported decision to disclose or not disclose the Sigg Application during the prosecution of one of Regeneron's patent applications has no bearing on whether Novartis employees defrauded the PTO during prosecution of the '352 Application nearly 10 years earlier, and cannot absolve Novartis of its own wrongdoing. *See Specialty Minerals, Inc. v. Pluess-Staufer AG*, 395 F.Supp.2d 109, 112 (S.D.N.Y. 2005) ("factually similar misconduct" by plaintiff insufficient to establish defendants' unclean hand defense); *MBIA Inc. Corp. v. Patriarch Partners VIII, LLC*, 842 F.Supp.2d 682, 713 (S.D.N.Y. 2012).[1]

Second, the information sought by Topic No. 36, including "factors considered by[] Regeneron" related to disclosure of prior art during prosecution of the '373 Application, is protected by attorney-client privilege and/or the work product privilege. Ex. 2 at 3; *Richards v. Kallish*, 2023 WL 8111831, at *2 (S.D.N.Y. Nov. 22, 2023) ("Because the communications with patent counsel were to prosecute a patent application, they are subject to the attorney-client privilege."). Indeed, Novartis has taken the position that its own "prosecution strategies" are protected by attorney-client privilege. Dkt. 169 at 3. Regeneron has not waived privilege with respect to its prosecution strategy during the'373 Application, including whether to disclose prior art, and should not be required to produce a witness to testify concerning an irrelevant topic for which there is minimal non-privileged scope. *DoorDash, Inc. v. City of New York*, 2025 WL 1212075, at *3 (S.D.N.Y. Apr. 25, 2025) (holding that a party is not entitled to deposition when

[1] Novartis has failed to identify any portion of the prosecution history in which Regeneron made statements concerning the disclosure in the Sigg Application regarding terminal sterilization. *See* Motion at 4-5, *infra*.

"the requested testimony would intrude upon an applicable privilege"); *Cerari S.r.L. v. Peju Province Winery L.P.*, 2020 WL 7261105, at *4 (S.D.N.Y. Dec. 10, 2020) (striking deposition topics that "exclusively concern matters protected by the attorney-client privilege"). While Novartis asserts that Topic 36 seeks non-privileged information, including the existence of a privileged investigation or the purported knowledge that individuals had of the Sigg Application, Novartis fails to explain how that non-privileged information is relevant to any defenses.[2]

Third, while Novartis now seeks Regeneron's general practices of prosecution, such information is plainly outside the scope of Topic No. 36. As written, Topic No. 36 is explicitly limited to the prosecution of one specific patent application—the '373 Application. Ex. 1 at 15. Novartis should be held to the topic that it actually requested from Regeneron, and its request to broaden the scope of the topic during the meet and confer process should be rejected. *Life Litigation*, 2023 WL 3244517 at *2 (holding that 30(b)(6) deposition topics must be described with "reasonable particularity"). And even if Novartis is correct that such information is within scope if it "explain[s] the non-disclosure" of the Sigg Application, Novartis is still not entitled to a witness because the reasons for Regeneron's non-disclosure is privileged.

Novartis's Position: Regeneron claims that Novartis committed fraud by failing to disclose "WO 2011/006877" (the "Sterilization Method Application") to the PTO while prosecuting the '631 patent. *See* Am. Compl. ¶¶ 112, 136, ECF No. 88. But in 2022, under similar circumstances, Regeneron failed to disclose the Sterilization Method Application to the PTO when prosecuting its '373 application, which, like the '631 patent, claims a terminally sterilized anti-VEGF prefilled syringe. Novartis's Topic No. 36 seeks relevant discovery regarding the '373

[2] To the extent Topic 36 covers the public prosecution record of the '373 Application, Novartis has failed to explain how such record relates to the fraudulent nature of Novartis's conduct.

prosecution to demonstrate that its own disclosure decisions were reasonable. *See In re Urethane Antitrust Litig.*, 2010 WL 5287675, at *5 (D. Kan. Dec. 17, 2010) (allowing discovery of plaintiffs' conduct to refute that "similar conduct by defendants is indicative of collusion").

The Sterilization Method Application claimed new methods for terminally sterilizing—sterilization of a product in its final packaging—a prefilled syringe containing a VEGF-antagonist using vaporized hydrogen peroxide. The '631 patent, on the other hand, claims a terminally sterilized syringe, prefilled with a VEGF-antagonist for intravitreal injection, with a very specific set of characteristics, *none of which are disclosed in the Sterilization Method Application*. *See* Ex. A at 13 (describing material, fill volume, silicone oil amount, particles per ml, and break-loose force of claimed syringe). While the syringe claimed by the '631 patent is terminally sterilized, the patent discloses that the syringe may be terminally sterilized by *known methods* and it does not purport to claim a *new method* of sterilization. Nonetheless, Regeneron alleges that, because the Sterilization Method Application discusses a syringe containing a VEGF-antagonist that is terminally sterilized using vaporized-hydrogen peroxide, Novartis patent attorneys committed fraud by not disclosing it to the '631 patent examiner. *See* Am. Compl. §§ F (ii)-(iii). Novartis contends that such non-disclosure was reasonable, and certainly not fraud.

Regeneron's '373 application claims "[a] method of treating an eye disorder in a patient" that includes "administering a [drug] to the patient *with a prefilled syringe*," where the drug "includes an *anti-VEGF agent*," and the pre-filled syringe is *sterilized* "with vaporized chemicals" including "*vaporized hydrogen peroxide*." *See* Ex. B. at 179–80. Regeneron knew of, but did not disclose, the Sterilization Method Application to the PTO examiner when it filed the '373 application. Instead, the examiner found the Sterilization Method Application himself and cited it nearly one year later. *See* Ex. C at 7. Regeneron successfully argued that the Sterilization Method

Application did not bar issuance of the '373 application, including because the former does not disclose *the specific features of the syringe claimed in the '373 application*. Ex. D at 11–12.

The aspects of the Sterilization Method Application that Regeneron claims overlap with, and make it material to, the '631 patent, also overlap with the '373 application. For that reason, Novartis's Topic No. 36 seeks testimony regarding the '373 prosecution—including the reasons why Regeneron did not disclose the Sterilization Method Application on its own and why Regeneron contended in the course of the prosecution that this prior art did not prevent allowance of the '373 claims. Such testimony is probative of whether Novartis's non-disclosure of the Sterilization Method Application during prosecution of the '631 patent was reasonable and not indicative of fraud. In turn, this bears on whether fraud is the "single most reasonable inference" to be drawn from Regeneron's presentation of circumstantial evidence (it is not). *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290–91 (Fed. Cir. 2011).

Regeneron's arguments that Novartis seeks testimony outside the scope of Topic No. 36, and that the Topic covers only privileged testimony are overstated. To the extent Regeneron's "general practices of disclosing prior art references" explain the non-disclosure of the Sterilization Method Application discussed above, these practices are within the scope of the Topic and are not privileged. Moreover, while the attorney-client privilege may shield certain aspects of the prosecution from discovery, the privilege does not apply to the public positions Regeneron took in the '373 prosecution. Nor can Regeneron assume, without investigation, that the reasons for Regeneron's non-disclosure are *necessarily* privileged. While Regeneron's attorneys may have determined that the Sterilization Method Application was immaterial to the '373 application, it is also possible that disclosure simply never occurred to Regeneron's prosecuting attorneys. Novartis is entitled to discover such non-privileged facts.

Respectfully submitted,

/s/ Anish Desai

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